UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: *State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al.*, Civil Action No. 03-11226-PBS	**Hon. Patti B. Saris**

DEFENDANTS DEY, INC. AND DEY, L.P.'S BRIEF IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT

PRELIMINARY STATEMENT

Defendants Dey, Inc. and Dey, L.P. (hereinafter "Dey") respectfully request that this Court grant partial summary judgment on the grounds set forth in Defendants' Joint Brief In Support of Partial Summary Judgment (the "Joint Brief") which would preclude any recovery of damages after January 1997 and cut off all liability after August 2002.[1] After January 1997, California's alleged damages were not caused by Dey but were rather the result of California's deliberate policy decision to pay rates it determined were necessary to meet its obligations of ensuring efficiency, economy, and access to quality care, as required by the Ninth Circuit. After August 2002, California's knowledge concerning the prices for the drugs at issue in this action was so complete that California could not possibly demonstrate either falsity or *scienter* under the California False Claims Act, Cal. Govt. Code § 12650 *et seq.* ("CFCA").

[1] In its motion for partial summary judgment, Dey relies on the evidence set forth in Dey's Rule 56.1 Statement ("Dey-SOF"), the Defendants' Joint Statement of Undisputed Material Facts ('C-SOF"), and the exhibits attached to the declaration of Sarah L. Reid (hereinafter referred to as "Reid Decl., Ex.__").

Dey further requests that the Court grant partial summary judgment in favor of Dey on all of California's claims that accrued after January 1999. The evidence in the record clearly demonstrates that from at least January 1999 on, Dey's public disclosures and disclosures directly to California, coupled with governmental studies into the pricing for many of Dey's drugs, preclude a showing of either falsity, *scienter*, or causation of damages for California's claims under the CFCA. Moreover, there is no evidence in the record at all that Dey made false pricing representations or that California suffered any damages for 37 of the 65 NDCs that are listed in the Dey complaint. Accordingly, Dey is entitled to summary judgment on California's claims regarding those drugs throughout the relevant time period.

I. PARTIAL SUMMARY JUDGMENT SHOULD BE GRANTED LIMITING THE TIME FRAME FOR ANY RECOVERY

Although Dey contends – and will show at trial – that the Government cannot recover on any of its claims, Dey is not liable as a matter of law after 1999. In an action under the CFCA, the government's "knowledge [of a fraud] effectively negates the fraud or falsity required by the [CFCA]." *Am. Contract Servs. v. Allied Mold & Die, Inc.* 94 Cal. App. 4th 854, 864, 114 Cal. Rptr. 2d 773, 780 (Cal. Ct. App. 2001). Likewise, "government knowledge" vitiates the requisite *scienter* under the CFCA: "there cannot be a knowing presentation of a false claim for payment where the government is fully aware of the facts surrounding the claim and approves it." *United States v. Shasta Servs. Inc.*, 440 F. Supp. 2d 1108, 1113 (E.D. Cal. 2006). The CFCA only permits recovery of damages that were caused "because of the act of [Defendants]". *See* Cal Gov't Code § 12651. The restrictive "because of" language limits California's recovery of damages to injuries that were proximately caused by the alleged false statements or false claims. *See Fassberg Constr. Co. v. Hous. Auth. of the City of Los Angeles*, 152 Cal. App. 4th

720, 750, 60 Cal. Rptr. 3d 375, 401-02 (Cal. Ct. App. 2007) (applying proximate cause standard to claims under the CFCA).

By 1999, California's knowledge of Dey's prices – gained through federal investigations as well as through disclosures made by Dey – was so extensive that there could no showing that Dey knowingly caused the submission of false claims, that any of the claims at issue were in fact false, or that Dey could have been the proximate cause of any damage to California.

A. Dey's WACs.

Dey has reported a WAC to pricing compendia such as First DataBank for each of the Subject Drugs since launch. (Dey-SOF ¶ 14.) Dey's WACs are the prices that Dey invoices wholesalers that purchase its drugs. (Dey-SOF ¶ 15) Over time, Dey decreased the WACs for the Subject Drugs as competition in the market place forced Dey to lower its prices. (Dey-SOF ¶¶ 14-16.) Since a number of wholesaler customers paid at or above WAC, the downward adjustments to the published WACs for Dey's drugs reflect downward adjustments in prices charged by Dey for its products. (Dey-SOF ¶¶ 16-17.)

Medi-Cal officials recognized that WACs were much more accurate predictors of market prices than AWPs. In a May 2004 e-mail, Kevin Gorospe, chief of the Medi-Cal Pharmacy Policy Unit at DHS since 2000, indicated that the manner in which Dey set its WACs was consistent with his understanding of WAC: "it appears that the average pharmacy obtains drugs at Wholesaler Acquisition Cost (WAC) less some percentage that is based on how quickly they pay their invoices…. The acquisition cost of generic drugs is often lower than this, however, the specific discount was not readily available." (C-SOF ¶ 55.) Indeed, on multiple occasions in the late 1990's, California considered moving to a reimbursement methodology based partially on WAC, understanding that this would result in lower payments for drugs. (C-SOF ¶¶ 33-35.)

Moreover, since Dey's WACs reflect prices that are actually charged for Dey's drugs, much of the so-called "spread" that California complains of is actually reflected in the difference between published AWPs and published declining WACs for Dey's drugs. (*See* Reid Decl., Ex. 9, (Bradford Decl.) Figures 1-29.) Indeed, by January 1, 1999, Dey was reporting AWPs and WACs that resulted in spreads of at least approximately 100% for all of the Subject Drugs. (*Id*.) Medi-Cal officials knew how to make this type of comparison, and in fact did so. In the same 2004 e-mail, Kevin Gorospe used WACs as an indicator of providers' actual costs to assess a proposed move in Medi-Cal's reimbursement methodology to AWP minus 20 percent:

> Based on this information, the Department has determined that the AWP is, on average, 26% higher than WAC for brand name drugs and 350% higher than WAC for generic drugs. Based on this information, if pharmacies are purchasing brand name drugs between WAC and WAC minus 2% and the Department reimburses the pharmacies at AWP minus 20%, on average, the pharmacies have approximately a 1-3% margin (profit) on brand name drugs and 180-182% margin on generic drugs.

(C-SOF ¶ 55.) WACs for the Subject Drugs are readily available in the same pricing compendia that California relies on for AWPs and California has WACs since at least 1996. (C-SOF ¶¶ 33-34.)

B. Price Notification Letters

Beginning in 1999, Dey began sending letters to State Medicaid programs, including DHS, describing what its published AWPs and WACs represented. (Dey-SOF ¶ 28.) These letters clearly stated that Dey's AWP was not a price actually charged or paid in the market place and that Dey's WAC was its undiscounted price to wholesalers. (Dey-SOF ¶¶ 30-31.) Dey has sent many letters containing this language to DHS since 1999. (Dey-SOF ¶ 35.) There is no issue of fact that Dey's practices with regards to setting WACs and AWPs were consistent with what was described in these letters. Moreover, Kevin Gorospe, the Chief of the Pharmacy Policy

Unit at DHS recalled receiving price notification letters like these, but never made any efforts to contact Dey regarding them or investigate further. (Dey-SOF ¶ 36.) Thus these prices could not reasonably be considered false; nor could Dey have knowingly caused the submission of false or fraudulent reimbursement claims by continuing to set its prices in the manner in which it told the Government it did.

C. Government Reports for the Dey Subject Drugs.

Beginning at least as early as 1995, the Office of Inspector General of the United States Department of Health and Human Services ("HHS-OIG") has repeatedly conducted and published studies comparing Medicare and Medicaid reimbursements to prices actually paid in the market place for the Dey Subject Drugs, particularly albuterol and ipratropium, which were readily available to California. HHS-OIG obtained pharmacy invoices, wholesaler catalog prices, and Federal Supply Schedule prices for the Dey Subject Drugs and analyzed them as a part of the publication of over ten OIG reports which directly address the drugs at issue here. (Dey-SOF ¶¶ 18, 24-26.) Kevin Gorospe testified that he would have reviewed reports issued by HHS-OIG as part of his job at DHS. (Dey-SOF ¶¶ 27.)

1. Albuterol Sulfate

HHS-OIG has published ten (10) reports *specifically* studying the acquisition cost of albuterol beginning in February, 1996, and subsequently in June, 1996 (two reports), December, 1997, August, 1998, November, 1998, June, 2000, January, 2001, March, 2002, and January, 2004. (Dey-SOF ¶ 18.) The almost yearly publication of albuterol report documented for California the actual ingredient cost for albuterol sulfate. For example, in "A Comparison of Albuterol Sulfate Prices" OEI 03-94-00392 (June 1996), HHS-OIG concluded that members of pharmaceutical buying groups could purchase albuterol sulfate for between 56 and 70 percent lower than the $0.43 per milliliter paid by Medicare at the time. (Dey-SOF ¶ 19.) In

California's parlance, this results in a spread of as much as 230%. In "Suppliers' Acquisition Costs for Albuterol Sulfate" OEI-03-94-00393 (June 1996), the HHS-OIG concluded that Medicare suppliers could acquire albuterol sulfate as low as $0.12 per milliliter, while the price paid by Medicare was $0.43 per milliliter. (Dey-SOF ¶ 20.) This difference between these two figures that were published by the HHS-OIG results in spreads of as much as 258%.

HHS-OIG made similar findings in later reports: in December, 1997, it reported that the actual AWP for albuterol sulfate in 1995 was $0.15, $0.17 lower than the $0.42 average Medicare reimbursement amount for that time (Dey-SOF ¶ 21); in August, 1998 it reported that Medicare will pay between 56 and 550 percent more for albuterol than prices available to the Department of Veterans Affairs (the "VA") and up to 333 percent more than some pharmacies pay to acquire albuterol (Dey-SOF ¶ 22); and in November, 1998, it reported that the median price for the VA to purchase albuterol sulfate unit dose was $0.12, while Medicare's median allowable price was $0.47, resulting in a 292 percent spread (Dey-SOF ¶ 23.)

2. Ipratropium Bromide

Beginning at least as early as 1998, HHS-OIG specifically studied the actual acquisition cost of another of the Subject Drugs, ipratropium bromide. (Dey-SOF ¶ 24.) In "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs" OEI-03-97-00293, the OIG found that the VA's median price for ipratropium bromide was $1.31, while Medicare's median allowable price was $3.34, resulting in a 155% spread. (Dey-SOF ¶ 25.) In 2001 and again in 2002, the OIG continued to find and to report that there were large spreads for ipratropium.[2]

[2] *See* HHS-OIG, "Medicare Reimbursement of Prescription Drugs" OEI-03-00-00310 (January 2001), which found that a median VA price of $0.84 per milligram, whereas the median Medicare allowable amount was $3.34, creating a spread of 297 percent. The report also found that the catalog price for ipratropium was $1.53, creating a spread of 118 percent. *See also* HHS-OIG "Excessive Medicare

3. Other Government Reports

As set forth more fully in the Joint Brief, since as early as 1977, HHS-OIG and California itself have issued reports examining the differences between AWP and providers' actual acquisition costs for drugs generally. (*See* Joint Brief at 2-5.) Most notably, in 1996 HHS-OIG published a report entitled "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the California Department of Health Services" (A-06-95-00062). (C-SOF at ¶ 32.) The report was the culmination of a two year survey of Medi-Cal providers' costs for prescription drugs that was conducted by HHS-OIG with the assistance of DHS employees. (Robben Decl., Ex. 20.) The report found that pharmacists' invoice prices for generic drugs were, on average, 41.4 percent below AWP. (C-SOF at ¶ 32.)

The MDL Court has previously held that the reports that resulted from these studies played a large role in putting private third-party payors such as Blue Cross/Blue Shield on notice that AWP did not represent actual acquisition costs as of 1997. *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20, 78 (D. Mass. 2007). If the reports were sufficient to apprise private third-party insurers that published prices did not reflect providers' acquisition costs, they were certainly sufficient to inform a sophisticated payor such as California.

D. Additional Information After 1999

In a case dealing with third-party private insurers, this Court held that "[b]y 2001, there was a perfect storm of information that reflected the size of the spreads, largely because of the

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Reimbursement for Ipratropium Bromide" OEI-03-01-00411 (March 2002); finding the median Medicare allowable cost for ipratropium bromide was $3.34, while the median VA price for ipratropium bromide was $0.66, resulting in a "spread" of 406 percent. The report also contained a chart, tracking the Medicare allowable amount against the VA prices between 1998 and 2001. Much like relationship between Dey's AWPs and WACs, the Medicare allowable amount, (which was the median AWP for all the generic sources of ipratropium bromide less five percent during that period) remains constant at $3.34, while the VA median price steadily decreases, starting at $1.29 in 1998 and dropping to $0.66 in 2001. The report also found that the median price for ipratropium appearing in wholesale catalogs was $0.82 per milligram, creating a spread of 307 percent between the catalog price and the Medicare allowable amount. (Dey-SOF 26.)

compelling information collected by the HHS Office of Inspector General ("OIG"). In addition, the press began to report on the rampant abuse of the AWP system." *In re Pharm. Indus. Average Wholesale Price Litig*., 491 F. Supp. at 41. For California, at least by 1999, there existed such a perfect storm of information relating to Dey. However, even after Dey began sending California letters regarding its AWPs and WACs in 1999, California continued to obtain pricing and other information regarding the Dey Subject Drugs.

Most notably, in 2000, the National Association of Medicaid Fraud Control Units ("NAMFCU") sent to Medi-Cal the results of an investigation it had conducted in conjunction with the United States Department of Justice into reported prices for infusion, injection, and inhalation drugs. (Dey-SOF ¶ 37.) The findings consisted of a comparison between published AWPs and prices available from wholesalers or Group Purchasing Organizations ("GPOs") for 400 drugs, including Dey's acetylcysteine, albuterol, cromolyn, and metaproterenol. (*Id*.) Almost all of the Dey drugs listed in the binder had spreads of well over 100 percent, with some going as high as 400 percent. (*Id*.) Following the study, NAMFCU and the DOJ began providing so-called "DOJ AWPs" to First DataBank so that Medicaid programs could use them, instead of manufacturers' reported prices, to reimburse for drugs. (Dey-SOF ¶¶ 37-38.) California ultimately elected not to implement these prices, out of concerns that the reduced payments would adversely impact access to quality care. In a memo to the Governor's office, DHS stated:

> The Department is concerned that providers affected by the new AWPs may discontinue serving [fee-for-service] Medi-Cal patients if the new prices are implemented. If this occurs, patients would either not have access to these important drugs or patients would be directed to a hospital to obtain them. The Department has already received correspondence from various advocacy groups such as hemophilia organizations and pharmacists organizations

> (see Attachment A) expressing their serious concerns over the new AWPs.

(Dey-SOF ¶ 39.) In a January 2001 response to a survey conducted by HHS-OIG regarding state Medicaid agencies' use of the DOJ AWPs, Kevin Gorospe confirmed that DHS chose not to implement them for reimbursement purposes because of concerns that the lower payments would cause providers to stop offering services to Medi-Cal beneficiaries. (Dey-SOF ¶ 40.)

* * *

As the evidence shows, by January of 1999, California was fully aware that the published AWPs for Dey's drugs substantially overstated providers' actual acquisition costs. Nonetheless, California chose to continue to used them to calculate reimbursement payments throughout the remainder of the relevant time period. Even today, California continues to rely on them. This choice may seem odd at first, but, as more fully set forth in Defendants' Joint Brief, California deliberately chose to pay providers significant margins above their actual acquisition costs to meet its legal obligation to ensure that the Medi-Cal program operated efficiently and economically, and that Medi-Cal beneficiaries had access to quality medical services. (*See* Joint Brief at Pt. II.C.) It is therefore patently unjust to hold Dey liable for provider reimbursement payments that California knowingly and deliberately made to meet its own policy goals.

II. SUMMARY JUDGMENT SHOULD BE ENTERED DISMISSING ALL CLAIMS FOR THE DEY NDCS WHERE CALIFORNIA HAS NOT PURSUED ITS CLAIMS

There is no evidence in the record that Dey made false statements concerning 37 of the 65 NDCs California attributes to it in the complaint, or that California suffered any damages relating to those NDCs. California's expert, Jeffrey Leitzinger, PhD., was retained to

> [d]etermine the amounts (total ingredient costs only) that Medi-Cal would have reimbursed if the report [AWPs] reasonably approximated the actual prices currently paid by the wholesalers'

> customers for those products over that same time period, insofar as such prices can be determined from Dey's business records.

Reid Decl. at Ex. 3, ¶ 5. Professor Leitzinger was also retained to "[c]alculate [California's] aggregate overpayment." *Id.* However, Professor Leitzinger's analysis was limited to only 28 NDCs for Dey's generic acetylcysteine, albuterol sulfate, cromolyn sodium, ipratropium bromide, and metaproterenol sulfate products. (Dey-SOF ¶¶ 4-6.) Professor Leitzinger made no attempt to determine what prices Dey should have reported for its atenolol, piroxicam, alprazolem, hydrocodone, theophylline, EpiPen, EpiPen Jr., DuoNeb, sodium chloride solution or sterile water products, nor did he attempt to calculate what, if any, "overpayments" California made for those products. (Dey-SOF ¶¶ 3-6.) California's "marketing" expert, Matthew Perri, III, PhD, RPh, testified that he was informed by California's counsel that the only Dey drugs at issue were acetylcysteine, albuterol sulfate, cromolyn sodium, ipratropium bromide, and metaproterenol. (Dey-SOF ¶ 7.) Since there is no other evidence in the record concerning what prices Dey should have reported for these NDCs, California cannot make the requisite showing of falsity under the CFCA for these drugs. Accordingly, Dey is entitled to judgment on California's claims relating to these NDCs as a matter of law.

A. California Cannot Establish Falsity For the 37 NDCs

California cannot establish the element of falsity under the CFCA for the 37 NDCs that Professor Leitzinger failed to analyze in his report. "For a false claim suit to succeed, the plaintiff must show that the claim was false, that is, contrary to an existing state of things." *United States ex rel. Local 342 Plumbers & Steamfitters v. Dan Caputo Co.*, 321 F.3d 926, 933 (9th Cir. 2003). In *Caputo*, the relator brought a False Claims Act claim against a subcontractor performing work on a federally funded project, alleging that the subcontractor falsely certified that it was paying its employees the prevailing wage, pursuant to federal law, when in fact it was

not. *Id.* at 927. The Ninth Circuit affirmed summary judgment in favor of the subcontractor, holding that the relator had failed to establish falsity because it had failed to show that the subcontractor was not paying the prevailing wage, as there was no showing of what the prevailing wage was. *Id.* at 933.

Likewise, California cannot establish "falsity" under the CFCA for the 37 NDCs because there is no evidence that the prices Dey reported for them were "contrary to an existing state of things." While Dey does not concede that Professor Leitzinger's determinations of the prices Dey should have reported for 28 NDCs he did consider is probative of Dey's liability, his complete failure to reach any such conclusion for the remaining 37 NDCs plainly shows that California cannot show what the "existing state of things" was with regards to the pricing for those drugs and, by extension, what price Dey should have reported. Accordingly, California cannot establish falsity for these NDCs, and its claims must be dismissed.

B. California Cannot Demonstrate That It Suffered Any Damages For the 37 NDCs

At the very least, California cannot establish that it has suffered any damages for the 37 NDCs that Professor Leitzinger failed to analyze. Under the CFCA, California is only entitled to recover damages for injuries that were proximately caused by the alleged false statements or false claims. *See Fassberg Constr. Co.*, 152 Cal. App. 4th at 750, 60 Cal. Rptr. 3d at 401-02 (applying proximate cause standard to claims under the CFCA). Again, while Dey does not concede that Professor Leitzinger's "overpayment" analysis for the 28 NDCs for albuterol, acytelcysteine, cromolyn, ipratropium, or metaproterenol are probative of any alleged injury California may have suffered, Professor Leitzinger's utter failure to engage in any level of "overpayment" analysis for any of the other NDCs, coupled with the absence of any other

demonstrable injury suffered by California related to these drugs, demonstrates that California cannot establish any damages for these drugs.

C. Dey Will Raise Its Objections to Professor Leitzinger's Expert Opinions At a Later Date

By limiting its motion to the 37 NDCs for which Professor Leitzinger performed no analysis, Dey does not waive any objection it has concerning the propriety of Professor's Leitzinger's analysis for the other Dey NDCs at issue in this action, its probative value, or its admissibility as evidence. Dey will address those issues in a separate *Daubert* motion at the appropriate time, along with other *Daubert* motions for California's other experts.

CONCLUSION

For the reasons set forth above, Dey respectfully requests that the Court grant this motion and enter judgment in favor of Dey on California's claims from January 1999 to the end of the relevant time period and enter judgment in favor of Dey on all of California's claims for all of California's claims arising from the NDCs not listed in paragraph 6 of Dey's Statement of Undisputed Material Facts, filed concurrently.

Dated: November 25, 2009

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on November 25, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Sarah L. Reid
Sarah L. Reid